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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant	:	Walter C. Fiers		
Application No.	:	08/452,658	Confirmation No. :	5499
Filed	:	May 25, 1995		
For	:	DNA SEQUENCES, RECOMBINANT DNA MOLECULES AND PROCESSES FOR PRODUCING HUMAN FIBROBLAST INTERFERON-LIKE POLYPEPTIDES		
Group Art Unit	:	1631		
Examiner	:	James Martinell		

New York, New York
June 24, 2005

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Sir:

Applicant/Appellant ("Applicant") files this Appeal Brief in support of his appeal from the final rejection of claims 31, 33 and 34 in the May 28, 2004 Office Action, which action was made FINAL. Applicant filed a Notice of Appeal on November 24, 2004 and paid the required fee.

Applicant has filed concurrently herewith a Petition for a five-month extension of time for filing this Appeal Brief and has paid the required fee under 37 C.F.R. §§ 1.136(a) and

1.17(a)(5). With the extension, the time for filing this Appeal Brief is extended up to and including June 24, 2005. Thus, this Appeal Brief is timely filed.

The Director is hereby authorized to charge $500.00 to Deposit Account No. 06-1075 (Order No. 000441.0031), in payment of the filing fee for the Appeal Brief, as required under 37 C.F.R. § 41.20(b)(2). The Director is also hereby authorized to charge any additional fees that may be due in connection with this Appeal Brief, or to credit any overpayment of the same, to Deposit Account No. 06-1075 (Order No. 000441.0031). A separate Transmittal Letter authorizing the Director to charge the Deposit Account is enclosed for these purposes (in duplicate).

In view of the arguments set forth below, the Board should find that the Examiner erred in rejecting claims 31, 33 and 34 under 35 U.S.C. § 102 (g) in view of the Sugano '567 or '859 patents and should reverse the Examiner and allow those claims.

I. Real Party In Interest

The real party in interest is Biogen Idec MA Inc., a corporation organized and existing under the laws of the Commonwealth of Massachusetts, and having an office and place of business at 14 Cambridge Center, Cambridge, Massachusetts 02142. The present assignee of this application is Biogen, Inc. Biogen merged with Idec and changed its name in November 2003. 37 C.F.R. § 41.37 (c)(1)(i).

II. Related Appeals And Interferences

There are three other appeals, known to applicant, his legal representative, or his assignee, that will directly affect or be directly affected by or have a bearing on the Board's

decision in the pending appeal. 37 C.F.R. § 41.37(c)(1)(ii). These appeals are being filed concurrently in the following co-pending applications:

i. U.S. Patent Application 08/471,646, filed June 6, 1995.

ii. U.S. Patent Application 08/253,843, filed June 3, 1994.

iii. U.S. Patent Application 08/449,930, filed May 25, 1995.

III. Status Of Claims

Claims 31, 33 and 34, set forth in Appendix A, stand rejected in this application and are on appeal. Claims 1-30 and 32 were previously cancelled. 37 C.F.R. § 41.37(c)(1)(iii).

IV. Status Of Amendments

Applicant has not submitted any amendments subsequent to the Examiner's May 28, 2004 Final Office Action. 37 C.F.R. § 41.37(c)(1)(iv).

V. Summary Of Claimed Subject Matter

Claims 31, 33 and 34 recite a method of treating human cancers or tumors by administering to a patient a composition comprising a recombinant IFN-β polypeptide produced by a DNA sequence that is operatively linked to an expression control sequence. 37 C.F.R. §41.37(c)(1)(v).

The independent claim involved in the appeal is:

Claim 31 recites (and dependent claims 33 and 34) recites a method for treating human cancers or tumors by administering to a patient a therapeutically effective amount of a composition comprising a pharmaceutically acceptable carrier and a recombinant polypeptide

produced by a non-human host transformed by a recombinant DNA molecule comprising a DNA sequence selected from the group of DNA sequences (a) that hybridize to the DNA inserts of four specifically-named recombinant DNA molecules, three of those molecules being contained in transfected host cells that were deposited in a recognized culture collection, or (b) that are degenerates of those DNA sequences. The claimed DNA sequences are operatively linked to an expression control sequence in the recombinant DNA molecule. Support for these claims can be found at, e.g., page 1, lines 10-19; page 12, lines 30-35; page 13, lines 8-30; page 94, lines 13-20; and claims 1, 5, 18, 28 and 30, as originally filed.

VI. Ground Of Rejection To Be Reviewed On Appeal

The ground of rejection to be reviewed on this appeal is the rejection of claims 31, 33 and 34 under 35 U.S.C. § 102(g) as being anticipated by Sugano et al., U.S. Patent 5,514,567 ("the Sugano '567 patent") or Sugano et al., U.S. Patent 5,326,859 ("the Sugano '859 patent"). 37 C.F.R. §41.37 (c)(1)(vi).

VII. Argument

The Rejection Of Claims 31, 33 and 34 Is Contrary To Law And Fact

The Examiner has finally rejected claims 31, 33 and 34 under 35 U.S.C. § 102(g) as being anticipated by the Sugano '567 patent or the Sugano '859 patent. Neither of the Sugano patents is 35 U.S.C. § 102(g) art to those claims.

A. The Sugano Patents Are Not 102(g) Art As A Matter Of Law

The Sugano patents are issued United States patents. As such, they are not 102(g) art as a matter of law and PTO practice.

35 U.S.C. §102(g) recites in pertinent part:

"A person shall be entitled to a patent unless –

(g)(2) before such person's invention thereof, *the invention was made in this country by another inventor* who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other" (emphasis added).

An issued United States patent cannot form the basis of a 102(g) rejection. It is not evidence of actual reduction to practice in this country. *See* MPEP § 2138:

"To qualify as prior art under 35 U.S.C. 102(g), . . . *there must be evidence that the subject matter was actually reduced to practice*, in that conception alone is not sufficient. See *Kimberly-Clark*, 745 F.2d at 1445, 223 USPQ at 607. While filing of an application for patent is a constructive reduction to practice, the filing of an application does not itself provide evidence necessary to show an actual reduction to practice of any of the subject matter disclosed in the application as is necessary to provide the basis for an *ex parte* rejection under 35 U.S.C. 102(g)" (emphasis added).

See also, In re Clemens, 622 F.2d 1029, 1038-39; 206 USPQ 289, 298-99 (CCPA 1980) (even a United States patent based on an earlier-filed patent application is not 102(g) art).

B. The Sugano Patents Are Not 102(g) Art To Applicant's Claims As A Matter of Fact

The earliest United States application that led to the Sugano patents was filed on October 27. 1980. Applicant's claims are entitled to at least the June 6, 1980 filing date of his UK patent application 80.18701.

The Examiner has never denied that applicant is entitled to such benefit. Indeed, in a January 14, 2003 Office Action, the Examiner rejected, under 35 U.S.C. §102(e),

substantially the same claims that now stand rejected over the very same Sugano patents. Applicant responded that the Sugano patents were not 102(e) art to his claims because he was entitled at least to the June 6, 1980 filing date of his UK application, which date preceded the October 27, 1980 earliest US filing date of the Sugano patents, i.e., the 102(e) date. *See* Reply to Office Action, July 14, 2003, pp. 3-4. In the face of this priority claim and argument, the Examiner withdrew the 102(e) rejections. *See* Office Action, November 7, 2003.

Accordingly, even if the Sugano patents were 102(g) prior art as a matter of law and PTO practice – which they are not – the rejection would still be in error because applicant has an earlier priority date than any United States filing date to which the Sugano patents may be entitled. For an *ex parte* 102(g) rejection, there must be a reduction to practice in the United States before applicant's invention. *See* 102(g), *supra*, p. 5.

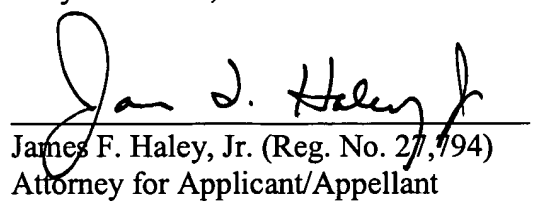
VIII. Claims Appendix

Appendix A sets forth claims 31, 33 and 34, which are pending in this application and are on appeal. 37 C.F.R. §37.41(1)(c)(viii).

IX. Conclusion

For all of the reasons set forth herein, applicant respectfully submits that the rejection of claims 31, 33 and 34 is erroneous and requests that the Board overturn it. All of the pending claims should be allowed.

Respectfully submitted,



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CLAIMS APPENDIX A
CLAIMS 31, 33 and 34, ON APPEAL

31. A method for treating human cancers or tumors comprising the step of administering to a patient in need of such treatment a therapeutically effective amount of a composition comprising:

1) a recombinant polypeptide produced by a non-human host transformed by a recombinant DNA molecule comprising a DNA sequence selected from the group consisting of:

(a) DNA sequences which hybridize to any of the DNA inserts of G-pBR322(Pst)/HFIF1, G-pBR322(Pst)/HFIF3 (DSM 1791), G-pBR322(Pst)/HFIF6 (DSM 1792), and G-pBR322(Pst)/HFIF7 (DSM 1793), and which code for a polypeptide displaying antiviral activity, and

(b) DNA sequences which are degenerate as a result of the genetic code to the DNA sequences defined in (a);

said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule; and

2) a pharmaceutically acceptable carrier.

33. The method according to claim 31, wherein said DNA sequence is selected from DNA sequences of the formulae:

ATGACCAACAAGTGTCTCCTCCAAATTGCTCTCCTGTTGTGCTTCTCCACTACAGCT
CTTTCCATGAGCTACAACTTGCTTGGATTCCTACAAAGAAGCAGCAATTTTCAGTGT
CAGAAGCTCCTGTGGCAATTGAATGGGAGGCTTGAATACTGCCTCAAGGACAGGAT
GAACTTTGACATCCCTGAGGAGATTAAGCAGCTGCAGCAGTTCCAGAAGGAGGACG
CCGCATTGACCATCTATGAGATGCTCCAGAACATCTTTGCTATTTTCAGACAAGATT
CATCTAGCACTGGCTGGAATGAGACTATTGTTGAGAACCTCCTGGCTAATGTCTATC
ATCAGATAAACCATCTGAAGACAGTCCTGGAAGAAAAACTGGAGAAAGAAGATTTC
ACCAGGGGAAAACTCATGAGCAGTCTGCACCTGAAAAGATATTATGGGAGGATTCT
GCATTACCTGAAGGCCAAGGAGTACAGTCACTGTGCCTGGACCATAGTCAGAGTGG
AAATCCTAAGGAACTTTTACTTCATTAACAGACTTACAGGTTACCTCCGAAAC, and
ATGAGCTACAACTTGCTTGGATTCCTACAAAGAAGCAGCAATTTTCAGTGTCAGAAG
CTCCTGTGGCAATTGAATGGGAGGCTTGAATACTGCCTCAAGGACAGGATGAACTTT

GACATCCCTGAGGAGATTAAGCAGCTGCAGCAGTTCCAGAAGGAGGACGCCGCATT
GACCATCTATGAGATGCTCCAGAACATCTTTGCTATTTTCAGACAAGATTCATCTAG
CACTGGCTGGAATGAGACTATTGTTGAGAACCTCCTGGCTAATGTCTATCATCAGAT
AAACCATCTGAAGACAGTCCTGGAAGAAAAACTGGAGAAAGAAGATTTCACCAGGG
GAAAACTCATGAGCAGTCTGCACCTGAAAAGATATTATGGGAGGATTCTGCATTACC
TGAAGGCCAAGGAGTACAGTCACTGTGCCTGGACCATAGTCAGAGTGGAAATCCTA
AGGAACTTTTACTTCATTAACAGACTTACAGGTTACCTCCGAAAC.

34. The method according to claim 31 wherein the polypeptide is selected from polypeptides of the formulae:
Met-Thr-Asn-Lys-Cys-Leu-Leu-Gln-Ile-Ala-Leu-Leu-Leu-Cys-Phe-Ser-Thr-Thr-Ala-Leu-Ser-Met-Ser-Tyr-Asn-Leu-Leu-Gly-Phe-Leu-Gln-Arg-Ser-Ser-Asn-Phe-Gln-Cys-Gln-Lys-Leu-Leu-Trp-Gln-Leu-Asn-Gly-Arg-Leu-Glu-Tyr-Cys-Leu-Lys-Asp-Arg-Met-Asn-Phe-Asp-Ile-Pro-Glu-Glu-Ile-Lys-Gln-Leu-Gln-Gln-Phe-Gln-Lys-Glu-Asp-Ala-Ala-Leu-Thr-Ile-Tyr-Glu-Met-Leu-Gln-Asn-Ile-Phe-Ala-Ile-Phe-Arg-Gln-Asp-Ser-Ser-Ser-Thr-Gly-Trp-Asn-Glu-Thr-Ile-Val-Glu-Asn-Leu-Leu-Ala-Asn-Val-Tyr-His-Gln-Ile-Asn-His-Leu-Lys-Thr-Val-Leu-Glu-Glu-Lys-Leu-Glu-Lys-Glu-Asp-Phe-Thr-Arg-Gly-Lys-Leu-Met-Ser-Ser-Leu-His-Leu-Lys-Arg-Tyr-Tyr-Gly-Arg-Ile-Leu-His-Tyr-Leu-Lys-Ala-Lys-Glu-Tyr-Ser-His-Cys-Ala-Trp-Thr-Ile-Val-Arg-Val-Glu-Ile-Leu-Arg-Asn-Phe-Tyr-Phe-Ile-Asn-Arg-Leu-Thr-Gly-Tyr-Leu-Arg-Asn, and Met-Ser-Tyr-Asn-Leu-Leu-Gly-Phe-Leu-Gln-Arg-Ser-Ser-Asn-Phe-Gln-Cys-Gln-Lys-Leu-Leu-Trp-Gln-Leu-Asn-Gly-Arg-Leu-Glu-Tyr-Cys-Leu-Lys-Asp-Arg-Met-Asn-Phe-Asp-Ile-Pro-Glu-Glu-Ile-Lys-Gln-Leu-Gln-Gln-Phe-Gln-Lys-Glu-Asp-Ala-Ala-Leu-Thr-Ile-Tyr-Glu-Met-Leu-Gln-Asn-Ile-Phe-Ala-Ile-Phe-Arg-Gln-Asp-Ser-Ser-Ser-Thr-Gly-Trp-Asn-Glu-Thr-Ile-Val-Glu-Asn-Leu-Leu-Ala-Asn-Val-Tyr-His-Gln-Ile-Asn-His-Leu-Lys-Thr-Val-Leu-Glu-Glu-Lys-Leu-Glu-Lys-Glu-Asp-Phe-Thr-Arg-Gly-Lys-Leu-Met-Ser-Ser-Leu-His-Leu-Lys-Arg-Tyr-Tyr-Gly-Arg-Ile-Leu-His-Tyr-Leu-Lys-Ala-Lys-Glu-Tyr-Ser-His-Cys-Ala-Trp-Thr-Ile-Val-Arg-Val-Glu-Ile-Leu-Arg-Asn-Phe-Tyr-Phe-Ile-Asn-Arg-Leu-Thr-Gly-Tyr-Leu-Arg-Asn.